

one
PHARMA S.A.



Your **One** CMO &
CDMO **Partner**

Company Presentation 2022

One Pharma S.A.



Company

- ❖ One Pharma is a standalone CMO & CDMO in Greece, with a manufacturing plant spanning 3.500m² in a total area of 15.000 m².
- ❖ One Pharma has produced over 200 different products for its clients and is exporting in more than 20 countries around the globe covering Europe, Canada, Middle East, Asia and the CIS market.
- ❖ One Pharma has 50+ employees.
- ❖ Eu-GMP and SFDA certified and in accordance with ISO: 9001:2015.
- ❖ At One Pharma we hold more than 25 years of experience in the pharmaceutical development & manufacturing fields.
- ❖ Offering Pharmaceutical, Food Supplement & Medical Devices Contract Manufacturing & Development Services.



Our Story

- ❖ Our facilities were originally built by Bristol Myers Squibb.
- ❖ 1994: Facilities acquired by Pharmanel Pharmaceuticals S.A.
- ❖ 2012: Production BU incorporated as One Pharma S.A..
- ❖ 2013: Completion of major refurbishment of the production facilities.
- ❖ 2019: One Pharma S.A. becomes a fully independent CMO/CDMO.



Mission

- ❖ Our Mission is to become one of the most responsive CMO/CDMO's in Europe.
- ❖ To make your complex projects simple for you.
- ❖ To deliver fast and with the outmost quality for our clients.
- ❖ To generate IP for our clients.
- ❖ Not just Generics.



Vision

- ❖ To add value to life through quality and expertise.
- ❖ To become the first choice CMO for our customers.
- ❖ To assist our clients in delivering top quality health services.
- ❖ To make our clients network worldwide.
- ❖ To Invest in long term partnerships.



Certifications

- ❖ GMP certificate by the Greek Health Authorities.
(last inspection Jul 2020 / no critical Findings)
- ❖ GMP certificate by SFDA.
(last inspection Sep 2017 / no critical Findings)
- ❖ GMP Audits:
Audits by clients e.g STADA, Oripharm, Pharmathen, Innovis, Pharos, Rosemont, Glenmark UK, Neuraxpharm, Sterimax, Advanz Pharma, Lupin etc.
- ❖ ISO 9001:2015 by Bureau Veritas Certification Hellas.



Flexible & Scalable

Who We Are

- ❖ One Pharma is a privately owned *CMO & CDMO* Specialized in:
 - Oral Solids
 - Oral Solutions
 - Cutaneous Solutions
 - Nasal Sprays
 - Oromucosal Sprays
- ❖ Our Facilities Support you from *Development to Market.*

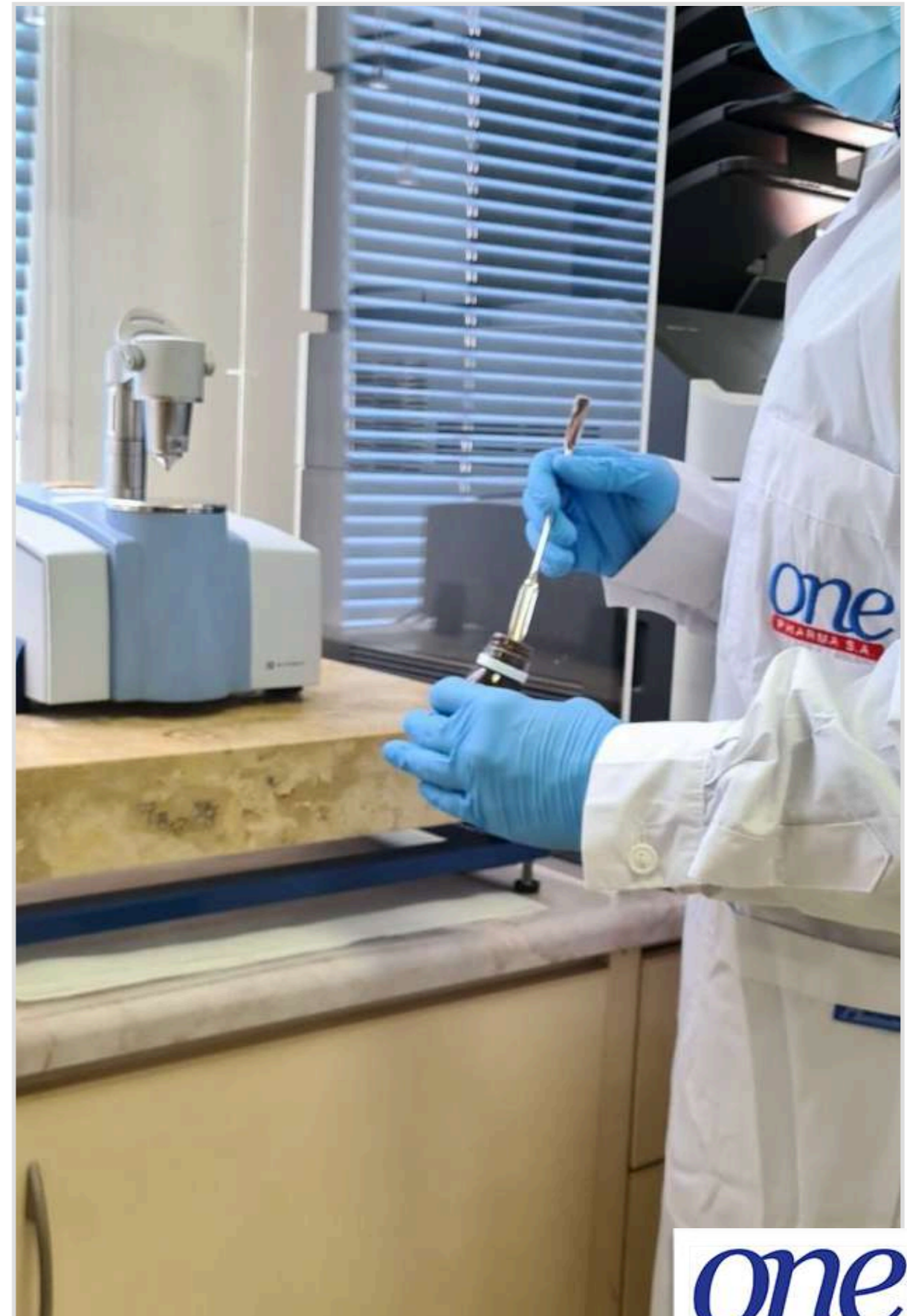


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Designed for Quality

Quality Control Department

- ❖ 100% with academic diplomas and constantly trained.
- QC Lab fully equipped with state of art analytical equipment: *HPLC, GC, UV, IR, Dissolution testers, pH meters, DSC, TOC, Incubators, Autoclave.*
- Independent microbiological laboratory.
- More than 300 Batches released / Year.



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Explore our Production Capabilities

Contract Manufacturing
Pharmaceuticals-Food
Supplements-Medical Devices
(Class 1)

Eu-GMP Production
GLP Lab



Facilities-Solids

❖ Mixing:

- 5-650kg batches
- ❖ Solid Dosage Forms-nominal capacity / shift / year.
 - Tablets : 800M
 - Capsules : 90M
 - Sachets : 10M
 - Powder for reconstitution in Bottle : 2M

❖ Processes

- High shear mixing
- Fluidized bed Drying & Granulation
- Film Coating



Machinery-Solids

- ❖ Solid Oral Forms
- ❖ Tablets:
 - IMA Kilian E150 plus, B Punches:
 - Fette P2020, D&B Punches
- ❖ Capsules:
 - IMA-Zannasi 12F
 - IMA-Zannasi 40F



Facilities-Liquids

- ❖ Liquid Mixing Volumes.
 - 30-3000lt batch size
 - Filling Capabilities:
 - Oral Solutions:
30-720ml
 - Nasal solutions / Oromucosal sprays / Ear preparations:
2-30ml
 - Liquids for Cutaneous use:
20-1000ml



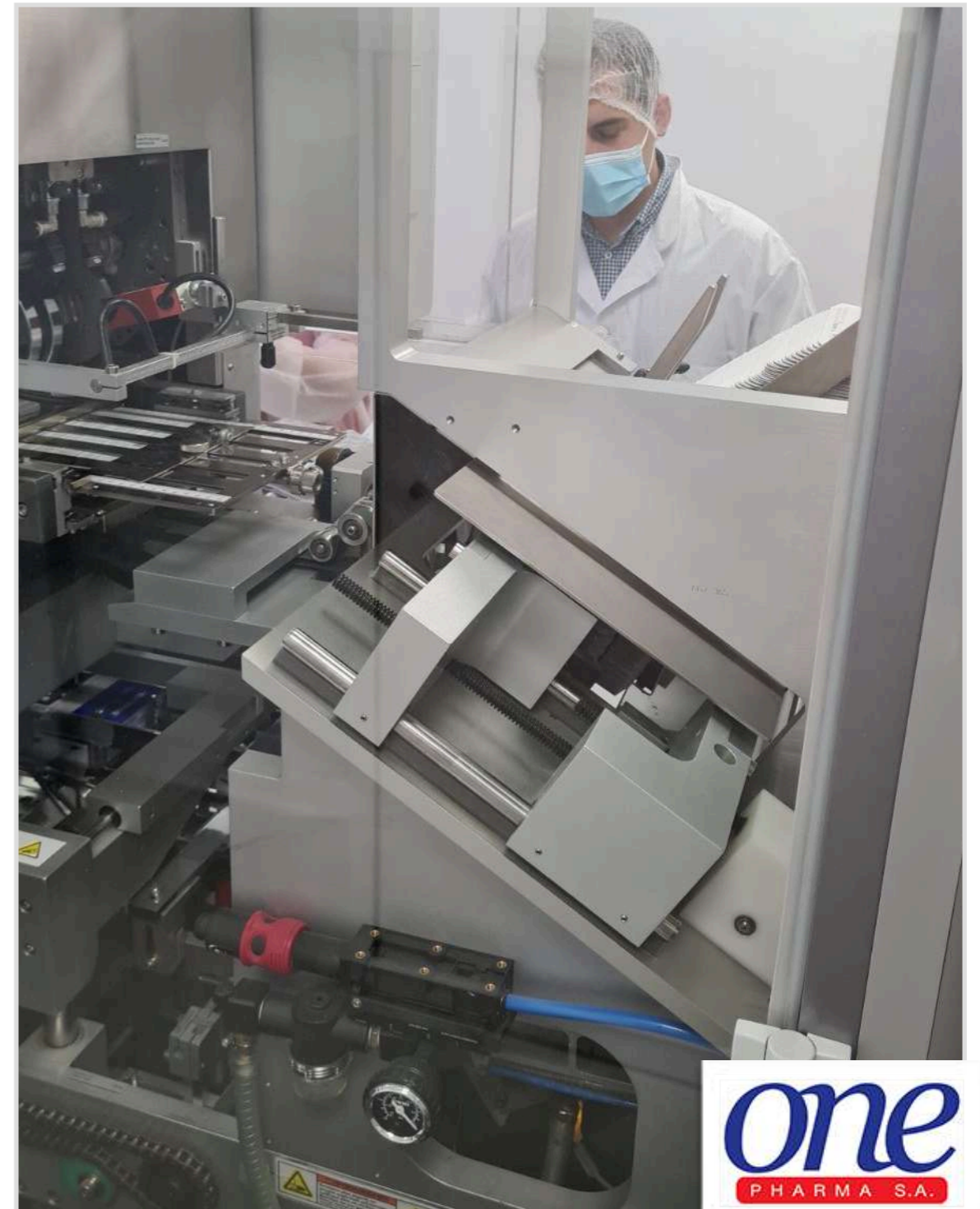
Capacity -Liquids

- ❖ Liquid filling lines: nominal capacity / shift / year.
- Nasal solutions / Oromucosal sprays / Ear preparations: 5M
- Liquids for Cutaneous use: 4M
- Oral solutions: 4M



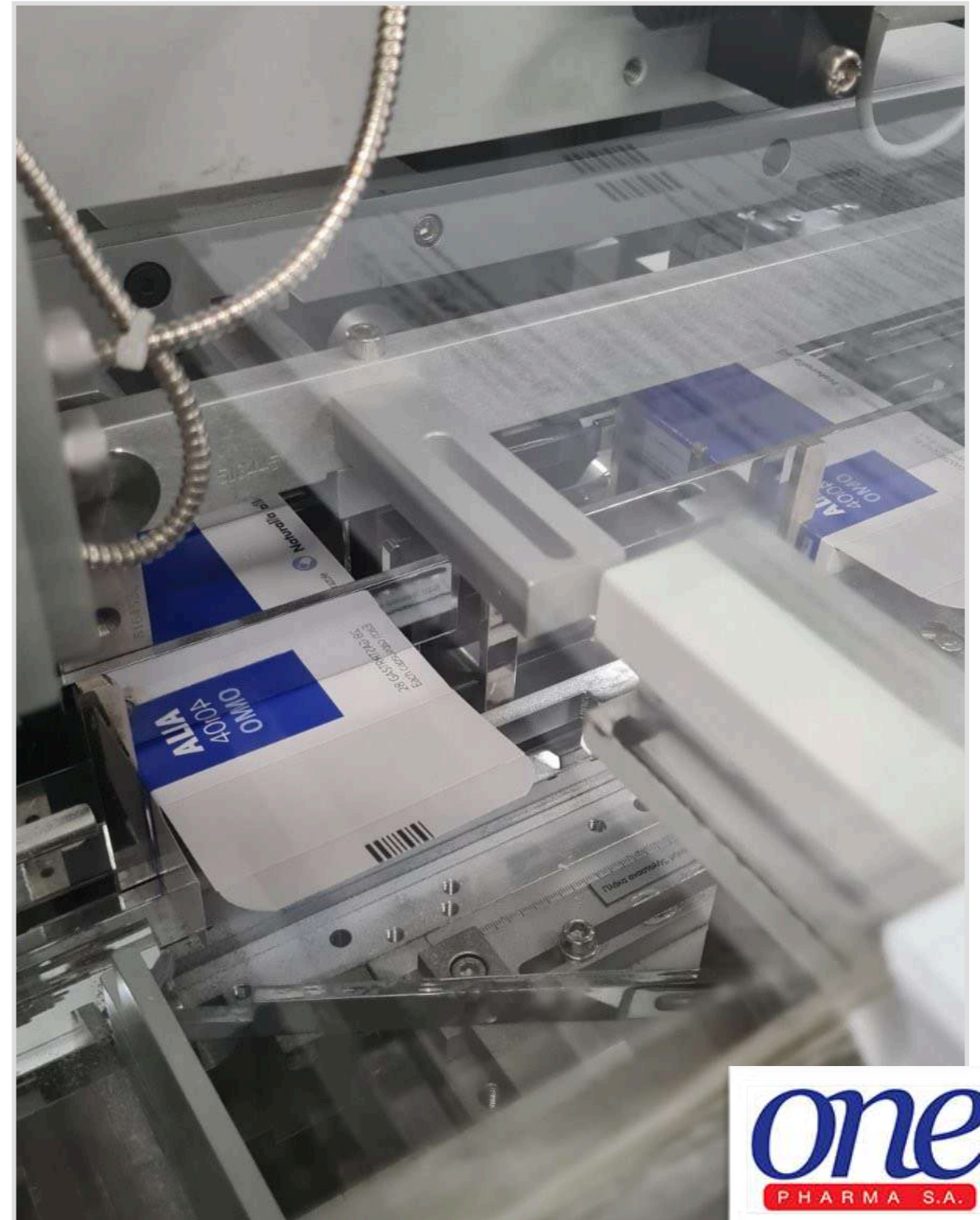
Packaging

- ❖ Blister: PVC-Alu, PE-Alu, PP-Alu, ALU-ALU, Aclar-ALU.
- Capacity nominal: 45M / shift / year
- ❖ Bottle filling: for capsules & tablets.
- Capacity nominal: 2,2M / shift / year



Why One Pharma

- ❖ One CDMO to offer you a wide range of forms and formats to suit your product's needs.
- ❖ 25 years of experience in pharmaceutical dosage formulations.
- ❖ Simple & Complex processes.



Our Specialities

- ❖ Photosensitive liquids
- ❖ Granules with taste masking
- Tableting & Powder processes
- Nasal preparations
- Oral solutions
- Oral solutions for reconstitution
(powder / granules in bottle)
- Sachets (powder / granules)





Formulation & Analytical Expertise

Contract Development

Experienced Team
Focused on Fast Delivery



Successfully completed projects

Contract Development

- ❖ More than 30 fully developed products completed (formulation & analytical development)
- ❖ More than 30 development projects completed for:
 - Analytical method development
 - Analytical method validation
 - Formulation development
 - Formula optimization



Full Scale Development Support

❖ Development Stage I

- *Product Design*
- *Patent Clearance*
- *Material Screening*

❖ Development Stage II

- *Reverse Engineering*
- *Preformulation Studies*
- *Formulation Studies*

❖ Development Stage III

- *Scale-up Study*
- *Submission Batches PV*

❖ Development Stage IV (Stability Services)

- *Long Term (zone II & IV a/b)*
- *In use Stability*
- *Photostability*



Research and Development

R&D-Pilot Lab

- ❖ Small scale R&D machines, scalable to our production machinery.
- ❖ R&D scale Fluidized bed dryer and granulator.
- ❖ R&D scale tableting machine.



Analytical Development

- Preapproval Analytical Development.
- Post Approval Analytical Upgrade.
- Post Approval Life Cycle Management.

Focus

- ❖ We are *Customer Focused & Adapt* to customer needs.
- ❖ We Aim on *fast* Project Delivery.
- ❖ We invest on *your* projects in order to improve:
 - *Efficiency*
 - *Cost*
 - *Quality*
- ❖ We can support you from small to big batches and small to big volumes.



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We are looking forward to hearing from
You

One Pharma Team

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